

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A liquid pharmaceutical composition for use in the treating of bone diseases, the composition being an aqueous solution comprising:

about 0.05% to about 35% by weight of ibandronaic acid or salts thereof;

about 0.1% to about 5% by weight of a pH regulating agent;

about 1% to about 15% by weight of a co-solvent;

about 0.005% to about 1.5% by weight of a conserving agent;

about 1% to about 90% by weight of a deionized water; and

~~excipients and at least one excipient~~ or pharmaceutically acceptable stabilizers, wherein the composition has a pH of about 2 to 7.

2. (Original) The composition of claim 1, wherein the pH regulating agent is selected from the group comprising acetates, phosphates, citrates, ascorbates, and bases or acids thereof.

3. (Original) The composition of claim 1, wherein the pH regulating agent is citric acid or the sodium salt thereof.

4. (Original) The composition of claim 1, wherein the co-solvent is selected from the group comprising glycol, glycerol and mixtures of same.

5. (Currently amended) The composition of claim 1, wherein the co-solvent is ~~propylene~~ propylene glycol.

6. (Original) The composition of claim 1, wherein the conserving agent is selected from the group comprising nipagin and nipasol.

7. (Currently amended) The composition of claim 1, wherein each 100 g of the aqueous solution comprises:

about 2 g to about 35 g of sodium ibandronate;
about 0.8 g to about 1.5 g of monohydrate citric acid;
about 15 g to about 25 g of ~~propilen~~ propylene glycol, and
water and pharmaceutically acceptable excipients, wherein the final pH of the composition is about 2 to about 3.

8. (Currently amended) The composition of claim 1, wherein each 100 g of the aqueous solution comprises:

about 0.15 g to about 0.30 g of sodium ibandronate;
about 0.3 g to about 0.7 g of sodium citrate;
about 6.5 g to about 7.5 g of ~~propilen~~ propylene glycol, and
about 0.001 g to about 0.1 g of nipagin;
about 0.002 g to about 0.5 g of nipasol;
about 1 g to about 2 g of sorbitol; and
water and pharmaceutically acceptable excipients, wherein the final pH of the composition is about 6.5 to about 7.

9. (Currently amended) A method of making the composition of claim 7, comprising the following steps:

- a) dissolving the citric acid in deionized water to form a solution;
- b) adding the ibandronate to the solution of step a) and agitating the solution until obtaining a complete dissolution;
- c) adding the ~~propilen~~ propylene glycol to the solution while maintaining said agitation;
- d) adding deionized water for bringing the solution to a final weight and sterilizing the solution by passing it through 0.22 μm filter.

10. (Original) The method of claim 9, further comprising, before step d), the step of measuring the pH of the solution and bringing the pH to about 2 to about 3.

11. (Currently amended) A method of making the composition of claim 8, comprising the following steps:

- a) dissolving the nipagin and nipasol in an amount of deionized water equivalent to the 50% of the final volume of the composition, at a temperature of about 70°C to about 85°C and under agitation;
- b) cooling down the solution 35°C and adding the sorbitol and the sodium citrate while agitating up to the complete dissolution;
- c) adding the ~~propilen~~ propylene glycol under agitation;
- d) adding the sodium ibandronate and agitating up to a complete dissolution;

12. (Original) The method of claim 11, further comprising, after step d), the step of bringing the pH of the solution to about 6.5 to about 7.

13. (Original) A method of making the composition of claim 1, comprising the following steps:

- a) dissolving the pH regulating agent in deionized water to form a solution;
- b) adding the ibandronate to the solution of step a) and agitating the solution until obtaining a complete dissolution;
- c) adding the co-solvent while maintaining said agitation;
- d) adding deionized water for bringing the solution to a final weight and sterilizing the solution by passing it through 0.22 µm filter.

14. (Original) The method of claim 13, further comprising, before step d), the step of measuring the pH of the solution and bringing the pH to about 2 to about 3.

15. (Original) A method of treating a bone disease in a patient in need thereof, the method comprising administering to the patient about 2.5 mg/day to about 10 mg/day of ibandronic acid or salts thereof in the composition of claim 1.

16. (Original) The method of claim 15, wherein the administration of the composition is selected from the group comprising via sublingual and via intranasal.